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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,947

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Yoshio Umezawa

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WENDEROTH, LIND & PONACK, L.L.P.

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EXAMINER

BURKHART, MICHAEL D

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,947	Applicant(s) UMEZAWA ET AL.	
	Examiner MICHAEL D. BURKHART	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,9-14 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9-14 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/15/2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt and entry of the amendment dated 11/15/2007 is acknowledged. After entry of the amendment, claims 1-5, 7, 9-14 and 21-26 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods wherein a fusion peptide (b) (e.g. as recited in claim 1) comprises a test protein, and vectors encoding such fusion peptides, does not reasonably provide enablement for such methods or vectors wherein the test protein is merely bound to the fusion peptide (b), or bound to the vector encoding fusion peptide (b). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **This rejection is applied to new claims 21 and 22 for reasons made of record in the Office Action dated 5/15/2007 regarding claims 1-4 and 8 (now amended or canceled).**

Claim 21 recites a recombinant vector (B) with a test protein bound thereto. To review, neither the specification nor the prior art teaches how to make and use the claimed recombinant vector (B) bound to any given arbitrary test protein. An analysis of the Wands Factors in the previous Office Action determined it would require undue experimentation to achieve this.

Response to Arguments

Applicant's arguments filed 11/15/2007 have been fully considered but they are not persuasive. Applicants essentially assert that the claims have been amended to indicate that the test protein is fused to peptide (b). However, this is not true for new claim 21, as set forth above.

Double Patenting

Applicant is advised that should claims 11-14 be found allowable, new claims 23-26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The only difference between the claims is that new claims 23-26 recite that the claimed cells comprise a vector expressing the fusion peptide(s) whereas claims 11-14 recite the cells comprising the fusion peptide. A review of the specification and the prior art reveals that the only known method for making and using the claimed cells, i.e. the only known method of getting the fusion peptide into a eukaryotic cell, is to transfect the cell with a vector encoding the fusion peptide(s). Thus, the enabled embodiments of claims 11-14 comprise the vectors recited in claims 23-26.

Claims 1-5, 7, 9-14 and 21-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 4-8 of U.S. Patent No. 7,166,447 in view of Ozawa et al (Anal. Chem., 2001, Vol. 73: pp. 2516-2521), Hamilton et al (U.S. Patent 6,780,599, effective filing date 5/12/2000), Simpson et al (EMBO reports, 2000),

and Martoglio et al (TICB, 1998). **This rejection is maintained for reasons made of record in the Office Action dated 5/15/2007, and for reasons set forth below.**

The limitations of the vectors and cells recited in new claims 21-26 are all addressed in the rejections over the '447 patent set forth in previous Office Action on pages 11-15, as the new claims are amalgamations of claims 7-20.

Claim Rejections - 35 USC § 103

Claims 1-5, 7, 9-14 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umezawa et al (WO 02/08766, 1/31/2002) as applied to claims 6, 8, 17, and 19 above, and further in view of Ozawa et al (Anal. Chem., 2001, Vol. 73: pp. 2516-2521), Hamilton et al (U.S. Patent 6,780,599, effective filing date 5/12/2000), Simpson et al (EMBO reports, 2000), and Martoglio et al (TICB, 1998). **This rejection is maintained for reasons made of record in the Office Action dated 5/15/2007, and for reasons set forth below.**

The limitations of the vectors and cells recited in new claims 21-26 are all addressed in the rejection over the above references set forth in previous Office Action on pages 17-21, as the new claims are amalgamations of claims 7-20.

Response to Arguments

Applicant's arguments filed 11/15/2007 have been fully considered but they are not persuasive. Applicants arguments address the above Double Patenting and 35 USC 103 rejections together, hence they are addressed together hereafter. Applicants essentially assert that: 1) the methods of Umezawa and Ozawa et al utilize protein splicing upon direct interaction

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of target proteins A and B, whereas the targeting signal peptide and test protein of the instant invention do not directly interact; 2) the interaction between fusion peptides (a) and (b) is indirect because the organelle lies between them.

Regarding 1), in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding 2), in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., indirect interaction between the fusion proteins) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Further regarding 1) and 2), it is abundantly clear from the teachings of the prior art (e.g. Umezawa and Ozawa et al) and the instant specification that in order for a fluorescent signal to be generated, the two fusion proteins must interact in a direct manner, i.e. the two half-inteins must interact. See Figs. 1 and 2 of the instant specification, and Figure 3 of Ozawa et al(b) (2001, Cur. Opin. Chem. Biol., of record). It is thus unclear, and applicants do not explain, why the skilled artisan would expect the fusion proteins to interact via the targeting signal domain(s). It is further unclear how the two fusion proteins, separated by an organelle membrane, could interact and generate a fluorescent signal, as suggested on page 14 of applicants response.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D. BURKHART whose telephone number is (571)272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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